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Docket: NRC-2020-0141

Reporting Nuclear Medicine Injection Extravasations as Medical Events

Comment On: NRC-2020-0141-0004

Reporting Nuclear Medicine Injection Extravasations as Medical Events; Notification of Docketing and Request for Comment

Document: NRC-2020-0141-DRAFT-0252

Comment on FR Doc # 2020-19903

Submitter Information

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Organization: UNC Chapel Hill

Government Agency Type: State

General Comment

See attached file(s)

Attachments

Extravasation Petition TB with reference

I am the statistician for the Epidemiology Research Team (ERT) at UNC Chapel Hill. I have had extensive experience working on a variety of clinical trials and epidemiological studies, from the study design and conception phase, through data collection, cleaning, and analysis.

Funded by the Department of Radiology, I was the lead statistician for the paper ***Quality Improvement Initiatives to Assess and Improve Positron Emission Tomography/Computed Tomography Injection Infiltration Rates in Multiple Centers***¹ which demonstrated that quality improvement initiatives resulted in a statistically significant decrease in infiltration rates. Implementing a random effects logistic regression that controlled for technologist-, center-, and patient-level correlations, we found that quality improvement initiatives reduced infiltration rates from 8.9% to 4.6%. This difference yielded a p-value of <0.0001, meaning that if we assume the null hypothesis is true, i.e. that there was no difference in infiltration rates before and after the quality improvement initiatives, there would be a less than a 1 in 10,000 chance that we would have observed a decrease in rates as large or larger than the decrease we observed. In other words, there is a very small probability that the improvement observed in this study was due solely to chance. It is my strong conviction, then, that infiltrations are reducible and I firmly support the petition to eliminate the extravasation reporting exemption.

1: Wong, T.Z., et al., Quality Improvement Initiatives to Assess and Improve PET/CT Injection Infiltration Rates in Multiple Centers. J Nucl Med Technol, 2019. 47: p. 326-331.